

**UNITED STATES DISTRICT COURT  
MIDDLE DISTRICT OF TENNESSEE  
NASHVILLE DIVISION**

<b>JERRY LANE BIRDSONG and</b>	)	
<b>BETTY BIRDSONG,</b>	)	
	)	
<b>Plaintiffs,</b>	)	
	)	
<b>v.</b>	)	<b>No. 3:10-01182</b>
	)	<b>Judge Campbell</b>
<b>ELI LILLY AND COMPANY and,</b>	)	
<b>AMYLIN PHARMACEUTICALS, INC.</b>	)	
	)	
<b>Defendants.</b>	)	

**MEMORANDUM**

Pending before the Court are Motions to Dismiss the Second Amended Complaint filed by Defendants Eli Lilly and Company and Amylin Pharmaceuticals, Inc. (Docket Nos. 41 & 43). By way of those Motions, Defendants seek dismissal of Claims Six through Eight which allege violations of the Tennessee Consumer Protection Act (“TCPA”), Tenn. Code Ann. § 47-18-101 *et seq.*; a claim for joint venture/joint enterprise liability; and a claim for concerted action. The Motions to Dismiss have been fully briefed (Docket Nos. 42, 44 & 50), and the Court grants the Motions with respect to Count Six, but denies the Motions with respect to Counts Seven and Eight.

**I. FACTUAL ALLEGATIONS**

This is an action to recover damages which were allegedly sustained by Plaintiffs after Plaintiff Jerry Birdsong used the prescription drug Byetta® and suffered pancreatitis. Mr. Birdsong was prescribed Byetta® by his endocrinologist, Dr. Michael Carlson, on December 1, 2009, and given samples of the drug. Mr. Birdsong injected the drug once daily, until he had a return visit to his doctor on December 30, 2009.

During Mr. Birdsong's return visit, Dr. Carlson doubled the prescription dosage of Byetta®. However, before taking the new dosage and, indeed, before even leaving the doctor's office, Mr. Birdsong experienced severe abdominal pain and was rushed to St. Thomas Hospital in Nashville, Tennessee, where he was diagnosed with acute severe pancreatitis. Since that diagnosis, Mr. Birdsong has undergone three endoscopic examinations, multiple CT scans, "has suffered cysts, nausea, fevers and symptomatic aortic aneurism," and now has chronic pancreatitis (Docket No. 34 ¶ 7), all of which he attributes to taking Byetta®.

Byetta® was developed, designed, manufactured, labeled, marketed and/or sold by Defendants. Byetta® is prescribed to control glucose levels in patients with type 2 diabetes mellitus and is self-injected into the stomach by the patient.

When Byetta® was first approved by the FDA in 2005 as a diabetes drug, there were no warnings in the package insert or prescribing information to physicians concerning acute pancreatitis. However, the FDA required Defendants to directly warn and advise patients about potential side effects and, since initial approval in April 2005, there were thirteen changes to the package insert, many of which added new and stronger warnings concerning the risk of pancreatitis.

In October 2009, two months before Mr. Birdsong began using Byetta®, the FDA approved a new package insert that specifically warned patients of the severe risk of pancreatitis. Among other things, the approved insert stated: "Serious side effects can happen in people who take BYETTA, including inflammation of the pancreas (pancreatitis) which may be severe and lead to death. Certain medical conditions make you more likely to get pancreatitis." (*Id.* ¶ 17).

Plaintiffs allege that the free sample of Byetta® given to Mr. Birdsong by Dr. Carlson

contained a patient education kit, but did not include the FDA required warnings concerning the risk of pancreatitis. They also allege Mr. Birdsong was not advised by Dr. Carlson of any risk of pancreatitis.

Based upon these events, Plaintiffs<sup>1</sup> filed suit against Defendants on a number of theories including negligence, strict liability, and violation of the TCPA. They also seek to hold Defendants liable for their and Dr. Carlson's actions (or inactions) under a joint venture/joint enterprise or concerted action theory.

With regard to the latter claims, Plaintiffs allege that Defendant Eli Lilly paid Dr. Carlson \$10,275 in 2009 as part of Lilly's "Healthcare Professional Educational Program." Under that program, "Lilly contracts with credentialed educators to help inform patients and their caregivers on the proper use of certain Lilly medications—such as those used with injection devices—that have been prescribed to the patients." (*Id.* ¶ 107). Plaintiffs assert that Dr. Carlson, having been paid by Lilly, was acting in a joint venture or joint enterprise to "help inform patients" about the risks of certain drugs, including Byetta®, that they "shared a common purpose to prescribe and dispense Byetta®," and that "the box and kit were jointly supplied, dispensed and controlled by Defendants and Dr. Carlson." (*Id.* ¶¶ 112-114). Finally, Plaintiffs allege that Dr. Carlson violated the applicable standard of care by failing to obtain informed consent (by not disclosing the risks associated with the use of Byetta®), and that Defendants are "vicariously liable for the acts and omissions of Dr. Carlson," including his providing Mr. Birdsong with a sample kit containing outdated warnings and risk information. (*Id.* ¶ 116).

## **II. STANDARD OF REVIEW**

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<sup>1</sup>Mrs. Birdsong has a derivative claim for loss of consortium.

In considering a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), the court must take “all well-pleaded material allegations of the pleadings” as true. Fritz v. Charter Township of Comstock, 592 F.3d 718, 722 (6<sup>th</sup> Cir. 2010). The factual allegations in the Second Amended Complaint “need to be sufficient to give notice to the defendant as to what claims are alleged, and the plaintiff must plead ‘sufficient factual matter’ to render the legal claim plausible, i.e., more than merely possible.” Id. (quoting Ashcroft v. Iqbal, 129 S.Ct. 1937, 1949-50 (2009)). “‘A legal conclusion couched as a factual allegation,’” however, “need not be accepted as true on a motion to dismiss, nor are recitations of the elements of a cause of action sufficient.” Id. (quoting Hensley Mfg. v. ProPride, Inc., 579 F.3d 603, 609 (6<sup>th</sup> Cir. 2009) and Bell Atl. Corp. v. Twombly, 127 S.Ct. 1955, 1965 (2007)).

### **III. LEGAL DISCUSSION**

#### **A. TCPA Claim – Count Six**

“In order to recover under the TCPA, the plaintiff must prove: (1) that the defendant engaged in an unfair or deceptive act or practice declared unlawful by the TCPA and (2) that the defendant's conduct caused an ‘ascertainable loss of money or property, real, personal, or mixed, or any other article, commodity, or thing of value wherever situated . . . .’” Tucker v. Sierra Builders, 180 S.W.3d 109, 115 (Tenn. Ct. App. 2005)(quoting Tenn. Code Ann. § 47-18-109(a)(1)). While “the TCPA is explicitly remedial and Tennessee courts are therefore required to construe it liberally to protect consumers in Tennessee,” id., the Court agrees with Defendants that the TCPA claim must be dismissed.

In Count Six of the Second Amended Complaint, Plaintiffs allege that Defendants “engaged in deceptive and fraudulent acts and practices injurious to the public interest” by influencing and

inducing physicians to prescribe Byetta® to unwitting patients. (Second Amended Complaint ¶ 101). Plaintiffs further allege that as a result of this practice, Mr. Birdsong used Byetta® and that this use led him to “suffer acute pancreatitis . . . sustained renal failure, and . . . a lifetime of sustained physical and financial damage including pain and suffering.” (Id. ¶ 102).

The damages Plaintiffs allegedly sustained flow from the medical complications and personal injuries Mr. Birdsong suffered from taking Byetta®. That is, Plaintiffs do not allege “an ascertainable loss of money or property” that exists independently of the personal injuries that Mr. Birdsong suffered. Because of that, Defendants move to dismiss the TCPA claim, arguing that Tennessee courts have held that claims for personal injury or wrongful death are outside the scope of the TCPA.

In support of their position, Defendants rely principally upon Kirksey v. Overton Pub., Inc. 804 S.W.2d 68 (Tenn. Ct. App. 1990) and Howard v. R.J. Reynolds Tobacco Co., 2005 WL 2088909 (E.D. Tenn. Aug. 25, 2005). Plaintiffs offer no cogent argument which persuades the Court that those cases were decided incorrectly or that Plaintiffs seek cognizable damages under the TCPA.

In Kirksey, the Tennessee Court of Appeals was presented with an appeal of a wrongful death case in which the jury rendered a verdict in favor of the defendants. On appeal, plaintiffs argued (among other things) that the trial court erred in striking their claim under the TCPA because, notwithstanding that the case stemmed from the wrongful death of their son, his life was “a thing of value” within the meaning of the Act. The appellate court rejected that argument, writing:

Our interpretation of T.C.A. § 47-18-109 is that a person would be allowed to bring an action for loss of money or property as a result of unfair or deceptive acts. We must hold that the General Assembly intended for the Consumer Protection Act to be used by a person claiming damages for an ascertainable loss of money or property

due to an unfair or deceptive act or practice and not in a wrongful death action.

Kirksey, 804 S.W.2d at 73.

Howard applied the foregoing holding to a personal injury action. Noting that “the Kirksey court did not discuss this issue in great detail,” but also that “other courts considering similar statutory language have concluded certain types of injuries fall outside the rubric of state consumer protection statutes,” the court in Howard held that a TCPA claim must be dismissed where a plaintiff “seeks to recover for injuries to his person resulting from [a defendant’s] alleged violation of the TCPA.” Howard, 2005 WL 2088909 at \*3.

It is true, as Plaintiffs argue, that the court in Howard did not dismiss the TCPA claim before it. However, the court did not do so because plaintiff was proceeding *pro se* and he did “not specifically mention his alleged medical injuries” in relation to his TCPA claim, making it theoretically possible that he was “asserting a cause of action under the TCPA based upon non-personal injuries resulting from [defendant’s] alleged unfair or deceptive acts[.]” Id. Here, Plaintiffs specifically link Mr. Birdsong’s TCPA injuries to his personal injury – acute pancreatitis and renal failure – which was allegedly the result of taking Defendants’ medication.<sup>2</sup> Therefore, Plaintiffs’ TCPA claim is dismissed.

#### **B. Joint Venture/Joint Enterprise Claim – Count Seven**

Defendants move to dismiss Plaintiffs’ joint venture/joint enterprise claims on three grounds:

(1) Plaintiffs allegedly mis-characterize the relationship between Dr. Carlson and Defendants; (2)

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<sup>2</sup>In a sense, Plaintiffs’ claims are not unlike a claim for medical malpractice because Plaintiffs repeatedly allege that Defendants failed to exercise reasonable care, Dr. Carlson violated the “applicable standard of care,” and Plaintiffs seek to recover damages for medical injuries which were allegedly brought about by Defendants’ actions. However, such claims, like claims for wrongful death or personal injury, cannot be recast as TCPA claims. Constant v. Wyeth, 352 F. Supp. 2d 847, 853 (M.D. Tenn. 2003).

Plaintiffs fail to allege an equal right to control the venture; and (3) Plaintiffs fail to allege that Dr. Carlson and Defendants intended to share in the profits of the alleged joint venture. The Court considers the arguments in turn.

In the Second Amended Complaint, Plaintiffs allege that Lilly entered into an agreement with the Office of the Inspector General of the United States Department of Health and Human Services which required it<sup>3</sup> to disclose payments made to physicians. (Second Amended Complaint ¶ 106). That disclosure revealed that Lilly paid Dr. Carlson \$10,275 in 2009 as part of its “Healthcare Professional Educational Program.” (*Id.* ¶ 107). Plaintiffs also quote a portion of Lilly’s website which describes “patient education programs” as follows:

Lilly contracts with credentialed educators to help inform patients and their caregivers on the proper use of certain Lilly medications—such as those used with injection devices—that have been prescribed to the patients. Educators may also provide disease and medication administration education to prescribing healthcare professionals and their office staff. All patient education is provided only upon referral by the prescribing healthcare professional.

(*Id.*). Based on the foregoing, Plaintiffs then allege:

108. In short, Dr. Carlson was paid by Lilly “to help inform patients” about Byetta® and this was pursuant to a formal contract.

109. Under these circumstances Lilly acted in a joint venture or joint enterprise with Dr. Carlson to “inform patients” about Byetta® and was acting in concert with Dr. Carlson “to help inform patients.”

110. Lilly had an FDA mandated duty to inform patients of the risks of Byetta® and paid Dr. Carlson to assist in this effort.

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112. Defendants and [Mr. Birdsong’s] treating physician shared a common purpose to prescribe and dispense Byetta and, more specifically to inform patients concerning risks of Byetta.

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<sup>3</sup>The Court notes that most of the allegations related to joint venture/joint enterprise are directed to actions taken by Lilly. While Defendant Amylin has also filed a Motion to Dismiss, it raises no independent grounds for dismissal, but merely rests on the arguments made by Lilly. Thus, the Court will not attempt to separate Plaintiffs’ claims against the Defendants, particularly since the Court does not know what relationship, if any, there may be between Lilly and Amylin, generally, or in relation to the marketing of Byetta®.

113. There was an agreement between Defendants and Plaintiffs' [sic] to inform patients concerning Byetta's labeling and risks. This agreement included a contract between Defendants and [Mr. Birdsong's] treating physician and payments to [Mr. Birdsong's] treating physician to inform patients of the risks of Byetta.

114. Defendants and [Mr. Birdsong's] treating physician each had an equal right "to control both the venture as a whole and any relevant instrumentality." Specifically the Byetta warnings, box and kit were jointly supplied, dispensed and controlled by Defendants and Dr. Carlson.

(Id. ¶¶ 108-110 & 112-114).

Defendants argue that "Plaintiffs' allegations that Lilly paid Dr. Carlson 'to help inform patients' and assist Lilly in fulfilling its 'FDA mandated duty to inform patients' are simply not true and are contradicted by the very source Plaintiffs cite." (Docket No. 42 at 7). Defendants also argue that "Plaintiffs' allegations that 'Defendants and [Mr. Birdsong's] treating physician shared a common purpose to prescribe and dispense Byetta and more specifically to inform patients concerning risks of Byetta' is inaccurate and irrelevant." (Id. at 9). Instead, Defendants insist that the patient education program upon which Plaintiffs rely is "designed to educate healthcare professionals on topics such as clinical trial data or disease management." (Id.).

Of course, whether Plaintiffs' allegations are true or accurate is not something which the Court can decide at this juncture since the well-pled factual allegations are accepted as true. Likewise, the Court cannot determine the real purpose of the education program at this point in time. It suffices for now that Plaintiffs allege that the program was designed to help doctors inform patients about Defendants' drugs, an allegation which is supported by the already-quoted language from Lilly's website which states that "Lilly contracts with credentialed educators to help inform patients and their caregivers on the proper use of certain Lilly medications[.]"

Nor can the Court conclude that Plaintiffs fail to adequately allege that Defendants and Dr. Carlson had an equal right to control the alleged joint venture. While it may be true that Dr. Carlson



alone had the authority to prescribe or to provide a free sample of Byetta® to his patient Mr. Birdsong, and while it may also be true that Dr. Carlson had no right to control the content of the labels accompanying Byetta®, Plaintiffs’ overriding contention insofar as they allege a joint venture/joint enterprise is that Defendants and Dr. Carlson shared a common purpose of getting Byetta® into the hands of patients and jointly undertook to inform patients about the risks of that medication.

Finally, Defendants argue that Plaintiffs cannot prevail on a joint venture/joint enterprise claim because they do not even allege that Defendants and Dr. Carlson agreed to jointly share in the profits of the alleged joint venture. In support of that position, Defendants cite Messer Griesheim Indus., Inc. v. Cryotech of Kingsport, Inc., 45 S.W.3d 588, 607 (Tenn. Ct. 2001) and the follow-up decision in Messer Griesheim Indus., Inc. v. Cryotech of Kingsport, Inc., 131 S.W.3d 470, 472 (Tenn. Ct. App. 2001). While the Tennessee Court of Appeals in both cases discussed profits in the context of an “implied partnership or joint venture,” the Court does not read Tennessee law as always requiring that there be an explicit agreement to share profits in order to prove that the parties engaged in a joint venture.

“In Tennessee, the ‘elements necessary to establish a joint venture are set forth in Cecil v. Harden, 575 S.W.2d 268 (Tenn. 1978) as: (1) a common purpose; (2) some manner of agreement among the parties to the joint venture; and (3) an equal right to control the venture and any relevant instrumentality.’” Pureworks, Inc. v. Brady Corp., 2010 WL 3723229 at \*10 (M.D. Tenn. Sept. 15, 2010)(citation and footnote indicating Cecil was abrogated on other grounds omitted). While Cecil makes no mention of profits, some Tennessee courts have noted that joint ventures and partnerships are related legal concepts and have indicated that partners/joint adventurers must agree to share

profits. See Messer Griesheim, 131 S.W.3d at 471; Wright v. Quillen, 909 S.W.2d 804, 808 (Tenn. Ct. App. 1995). Other Tennessee courts, quoting or citing Cecil, have discussed the elements required to prove a joint venture but do not mention profits as being among them. Fain v. O'Connell, 909 S.W.2d 790, 793 (Tenn. Ct. App. 1995); Bryant v. McCord, 1999 WL 10085 at \*12 (Tenn. Ct. App. 1999); Dewberry v. Maddox, 755 S.W.2d 50, 56 (Tenn. Ct. App. 1988). Having considered the foregoing cases and most especially the Tennessee Supreme Court's decisions in Cecil and Fain, the Court concludes that, for Plaintiffs to prevail on their joint venture/joint enterprise claim, it is not absolutely essential that they prove that there was an agreement to share profits. This is particularly so because, as the court in Fain observed, the Tennessee law surrounding joint ventures was developed primarily in the context of automobile accidents, Fain, 909 S.W.2d at 793, and the issue of sharing profits does not often come into play in such circumstances.

Nevertheless, as both Cecil and Fain make clear, “[l]iability predicated on a joint venture theory of mutual responsibility is not imposed in instances in which the parties join together purely for pleasure, but is reserved, rather, for cases in which the parties associate for business, or expense sharing, or some comparable arrangement.” Fain, 909 S.W.2d at 793 (quoting Cecil, 575 S.W.2d at 272). While present Plaintiffs do not specifically allege that Dr. Carlson and Defendants agreed to share profits, the fair inference to be drawn from their allegations is that Dr. Carlson and Defendants reached a mutually beneficial agreement and arrangement which placed Byetta® in the hands of patients like Mr. Birdsong. The joint venture/joint enterprise claim will not be dismissed.

#### **B. Concert of Action Claim – Count Eight**

In Bryant, the Tennessee Court of Appeals stated that Tennessee recognizes an independent tort claim for “concert of action” and that such a claim arises ““when two or more persons engage

in an unlawful act and one of them commits a serious civil injury upon a person not engaged therein[.]’” Bryant, 1999 WL 10085 at \*12 (quoting Huckeby v. Spangler, 521 S.W.2d 568, 573 (Tenn.1975)). Under a concert of action theory, “‘one is liable if he (a) does a tortious act in concert with the other or pursuant to a common design with him, or (b) knows that the other's conduct constitutes a breach of duty and gave substantial assistance or encouragement to the other so to conduct himself, or (c) gives substantial assistance to the other in accomplishing a tortious result and his own conduct, separately considered, constitutes a breach of duty to third person.’” Id. (quoting Restatement (Second) of Torts § 876(c)).


Defendants move to dismiss Count Eight on the grounds that Plaintiffs merely assert “a recitation of the elements of a concert of action theory set forth in the Restatement (Second) of Torts, and fail to identify the facts that serve as the basis for their claim.” (Docket No. 42 at 11). Although the factual allegations in Count Eight may be somewhat sparse, Plaintiffs explicitly incorporate by reference the other allegations in the Second Amended Complaint and specifically those allegations which support their joint venture/joint enterprise claim as pled in Count Seven. When the allegations are read in Plaintiffs’ favor, Plaintiffs sufficiently plead a plausible claim under a concert of action theory.

Plaintiffs allege that Dr. Carlson and the Defendants acted in concert with each other to advise patients of the risk of Byetta®, but that Mr. Birdsong was not informed of the substantial risk for contracting pancreatitis. This allegedly occurred at a time when it was well-known that pancreatitis was a possible side-effect of taking Byetta®, and in spite of the fact that the FDA mandated new and more stringent warnings two months before Mr. Birdsong began taking Byetta®. Additionally, the allegations and reasonable inferences to be drawn from the Second Amended

Complaint suggest that Defendants acted in concert to distribute (including giving free samples to doctors like Dr. Carlson) and to promote and expand the market for Byetta®, while all along attempting to downplay the risks from taking that drug. See Second Amended Complaint ¶¶ 19-30). Such allegations, if true, suggest that Defendants and Dr. Carlson may have engaged in unlawful acts which ultimately result in injury to Mr. Birdsong, and, thus, dismissal of Plaintiffs' concert of action claim is unwarranted.

### **III. CONCLUSION**

On the basis of the foregoing, Defendants' Motions to Dismiss are granted in part and denied in part. The Motions are granted with respect to Plaintiffs TCPA claim as set forth in Count Six, but denied with respect to Plaintiffs' joint venture/joint enterprise claim as set forth in Count Seven, and with respect to Plaintiffs concert of action claim as set forth in Count Eight of the Second Amended Complaint.

  
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Todd J. Campbell  
United States District Judge